K040339

APR - 8 2004

510(k) Summary of Safety and Effectiveness

The Brachytherapy Strand Device

The following 510(k) Summary of Safety and Effectiveness is provided according to the requirements of 21 CFR 807.92.

Date

February 06, 2004

Company Name

BEBIG Isotopen- and Medizintechnik GmbH
Robert Rössle Str. 10
13125 Berlin, Germany
phone: ++49 30 94 10 84-0
fax: ++49 30 94 10 84-112

Official Contact

Sven Langer
Regulatory Affairs

Device Name

Proprietary Name:	Brachytherapy Strand Device
Common Name:	Brachytherapy seed strand
Classification :	Class II, 21 CFR 892.5730, Radionuclide Brachytherapy Source, KXK

Predicate Devices used for Substantial Equivalence

Device	Premarket #
I-125 Rapid Strand Model 7000	K982226
BEBIG brachytherapy I-125 source	K021343
Theraseed® Palladium-103 Implant Model 200	K010283
Vicry Rapide Suture	K944110

Intended Use

The BEBIG I-125 sources are intended for use in the treatment of tumors, with radioactive sources within or in close proximity to the tumor.

Indications for use

The Brachytherapy Strand Device is indicated for tumors with any of the following characteristics:

- o Localized
- o Unresectable
- o Low to Moderate Radiosensitivity

The tumors may be of the following type:

- o Superficial
- o Intrathoracic
- o Intra-abdominal
- o Lung, Pancreas, Prostate, Head and Neck
- o Residual following external beam radiation or excision of primary tumor
- o Recurrent

Description

The Brachytherapy Strand Device is used for the treatment of localized tumors and is placed into a body cavity or tissue. It consists of a pre-sterilized kit containing a prostate seeding needle and a custom-loaded strand of seeds spaced at a precise distance within absorbable suture. The spacers are made from the same material as the sutures. The customized strand can contain a variable number (1-12) of seeds and/or seeding spacers (maximum 12 components per strand). The stranded Pd-103 and I-125 implants are placed inside the needle. The needle is made from 18 gauge stainless steel

Comparison to predicate device

Both devices are composed of seeds incorporated within suture material, with spacers separating the seeds. The suture material and spacers are completely biodegradable within the body.

Characteristics	Brachytherapy Strand Device	RAPID Strand
Premarket Notification	Subject of this 510(k)	K030594
Sealed source	BEBIG brachytherapy I-125 source cleared by K021343 and TheraSeed® cleared by K010283	OncoSeed cleared by K914281
Seeding Spacer	Absorbable Seeding Spacer made from medical grade Poly-(glycolide-co-L-lactide) 90:10 and moulded under class 10,000 cleanroom conditions.	Commercially available absorbable Seeding Spacer made from Poly(glycolide-co-L-lactide) 90:10, cleared by K013964
Seed carrier	Coated VICRYL Polyglactin 910 (Poly(glycolide-co-L-lactide) 90:10) Synthetic absorbable suture, cleared by K022269, thermally stiffened..	
Sterilization	Gamma sterilization (also used for Vicryl Rapide Suture, cleared by K944110)	EtO sterilization
Packaging	Strands preloaded in implantation needle.	Strands housed in plastic spacing jig.

Summary

Based on the information provided herein, we conclude that the Brachytherapy Strand Device is substantially equivalent to a legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2004

Mr. Sven Langer
Regulatory Affairs
BEBIG, Isotopen-und
Medizintechnik GmbH
Robert-Rossle-Straße 10
D-13125, Berlin
GERMANY

Re: K040339
Trade/Device Name: Brachytherapy Strand Device
Regulation Number: 21 CFR 892.5730
Regulation Number: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: February 6, 2004
Received: February 11, 2004

Dear Mr. Langer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: Brachytherapy Strand Device

Indications for Use:

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- o Localized
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Prescription Use___X___ (Part 21 CFR 801 Subpart D) AND / OR Over-The –Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040339